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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/005,902

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Dale Brown

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7185

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

09/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/005,902

Applicant(s)

BROWN ET AL.

Examiner

Shirley V. Gembeh

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/14/02, 7/15/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/11/07 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/14/02 and 7/15/02 have been reviewed. Items CA and CA-CJ of 3/14 and 7/15/02 have been lined through.

Status of claims:

Claims 2-7 and 9-14 have been cancelled and new claims 15-25 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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The claims are now broader than what was originally claimed. Treating gingival detachment as recited in the instant claim 15 now includes self administering or administering by a physician, dental hygienist etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller, US 5,129,824 ('824) taken with Hill, US 5,993,784 (784) and Hill et al., US 5,057,309 ('309) in view of Kim et al., US, 6,045,800 ('800).

Keller teaches a method to treat periodontal disease (at col. 2 lines 39-45), where the patient can easily administer medication to the infected site (see col. 2 lines

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49-60), as in the current claim 1, by physically removing biofilms (plaques) from the subgingival, supragingival and interproximal tooth surfaces on a daily basis (at col. 7 lines 20-32) with brushing, flossing or with an interdental brush (proxy brush). See col. 3, lines 4-19, as recited in instant claims 15.

'784 teaches cleaning the gingival tooth surfaces with a toothbrush (at col. 1, lines 65+, see also figures 1-4a), which shows a tooth brush with a five ribs and grooves. In addition, Hill teaches administering soft abrasives onto gingival surfaces- supragingival (col. 2 lines 4-50) (on/base) and subgingival-deepened gingival sulcus (periodontal pockets) with a toothbrush. The reference is directed to brushing with a channeled bristle toothbrush and a soft abrasive toothpaste (see col. 2 lines 57-60).

'309 teaches the combination of nonionic surfactants with coating materials (see col. 5, lines 46-47), wherein the coating material is polydimethylsiloxane, as required by instant claims 20-22. See col. 14, lines 11-17. One of ordinary skill in the dental art would have been motivated to add a coating to the dental care gel, proxy gel or the floss to shield irritated or exposed inflamed tissue (see US 5,098,299, col. 2, lines 51-52).

Kim et al. teach the subject matter of current claims 23-25, which is directed to adding an anti-inflammatory agent to the dentifrices (see col. 1 lines 54-65), where the therapeutic substance/agent is chlorohexidine gluconate, cetylpyrridium chloride, triclosan (cited at col. 1 lines 54-57).

Although the above cited references do not per se teach the use of a proxy gel, one of ordinary skill in the art would have been motivated to have a gel, as evident by Kleinberg et al., US patent 6217851, because dental care products are made in paste or

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gel (see col. 5, lines 26-30). One of ordinary skill in the art would have been motivated to treat gingival detachment of at least 3 mm using a ribbed and bristle toothbrush with a non abrasive tooth paste because the prior art teaches the use of a ribbed toothbrush for the removal of plaque. One of ordinary skill in the art would have been motivated to use the teaching of Keller et al., drawn to the use of a floss to physically remove plaques and at the same time release therapeutic agents to the surface for treating bleeding, or for treating microbial/bacterial infection in the area.

Moreover, it is well within the level of one having ordinary skill in the art to be motivated to use more than one device a day to maximize the effect of the drug and the removal of the plaque as this would prevent surgery to the affected area (see the examples in cols.7, and 8) of the '824 reference. It is also a way of continuous treatment, i.e., using a tooth brush in the morning and evening, coupled with in-between flossing. This is particularly important to the treatment of disease of the affected area, which is yet another well known practice among those skilled in the art.

One of ordinary skill in the art would have combined the teachings of the '824, '784 and '309 references with that of '800 by adding the anti-inflammatory agent to the gel (see col. 2 lines 1-15) at the time the claimed subject matter was made, because it will inhibit the production of the prostaglandins, which is an inducing agent for periodontal disease. The reference '824 also teaches the addition of other medicaments to the dental device (see col. 7 lines 35-40 of the '824 reference); therefore, one of ordinary skill in the art would have been motivated to add an anti-

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inflammatory active agent to the delivery device to decrease prostaglandin production and inflammatory activity with a reasonable expectation of success.

Thus, the claimed invention was prima facie obvious to make and use at the time it was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembel whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**

9/13/07